SpineJack®
Controlled Anatomical Restoration
Introducing the Surgical Technique
The SpineJack® System is designed for the Anatomical Reduction of Vertebral Compression Fractures (VCF type A1, A2 and A3.1 Magerl Classification), with or without underlying pathologies affecting the bone quality such as osteoporosis and malignant lesions (Myeloma or osteolitic metastasis).
**SpineJack® Surgical Technique**

### Introduction

Pre-operative SpineJack® Information

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Implants Preparation Kit / Expansion Kit

Guide wire (blunt)

Guide wire (threaded)

Square awl

Working cannula

Reamer with working cannula preassembled

Template

- KP006 (Preparation kit Ø 6.5mm (unit))
- KP001 (Preparation kit Ø 5.0mm (unit))
- KP004 (Preparation kit Ø 4.2mm (unit))

- KE006 (Expansion kit Ø 6.5mm (unit))
- KE001 (Expansion kit Ø 5.0mm (unit))
- KE004 (Expansion kit Ø 4.2mm (unit)) + TC04004*

*For the SpineJack® 4.2mm, a TC04004 (Adaptor) will be included in the SpineJack® Expansion Kit (KE) boxes. It will connect to the TC05005 or to an injector.

Full control over positioning

The instrumentation has been developed to always give full control over the implant positioning: as soon as the reamer is inserted it is possible to know and adjust what will be the final implant positioning.
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SpineJack® Implant Dimensions

SpineJack®

6.5

Plate length: 20.2mm
Maximal expansion: 20mm
Insertion: Ø6.5mm
Implant tube: Ø2.9mm
Total length: 28mm

SpineJack®

5.0

Plate length: 19mm
Maximal expansion: 17mm
Insertion: Ø5.0mm
Implant tube: Ø2.5mm
Total length: 25mm

SpineJack®

4.2

Plate length: 14mm
Maximal expansion: 12.5mm
Insertion: Ø4.2mm
Implant tube: Ø2.2mm
Total length: 20mm
Fracture mobility assessment
SpineJack® is indicated for the treatment of mobile vertebral compression fractures, and therefore the assessment of the fracture’s mobility prior to operating is recommended in order to maximize fracture reduction.

Vertebra dimensions
In order to ensure an optimal fit of SpineJack® implants, a CT scan of the vertebral body prior to surgery must confirm the adequacy of the vertebral dimensions. Access to the vertebral body requires a pedicle with a minimum diameter of 5mm (diameter KE 004 + 0.8 mm => 5mm):

- 7.3 mm
- 5.8 mm
- 5.0 mm

Implant positioning
The placement of 2 implants is often recommended to achieve optimum anatomical restoration. However, depending on the type of fracture to be treated, the practitioner may decide to place only one SpineJack® implant.

The extent of fracture reduction depends largely on the positioning of the implant within the vertebral body. It is therefore recommended to map the optimal placement of the implants prior to surgery.

Patient positioning
Patient is positioned in prone position. Patient has to be positioned to minimize loads on the fractured vertebra.

A hyper-lordotic position is recommended for lumbar fractures.

Anaesthesia
General, local or regional anaesthesia can be used depending on clinicians’ preferences and patients’ conditions.

TIPS & TRICKS
1. Please assess pre-operatively on your CT scans, for all levels to be treated with SpineJack® (especially in smaller thoracic vertebrae):
   1. The inner diameter of the pedicle in order to define the biggest size implant (including working cannula) which can potentially be inserted through the pedicle.
   2. The inner diameter of the vertebral body in order to define the biggest size implant which can be opened in the vertebral body.
   3. The ideal positioning of the SpineJack implant(s) in all different types of fractures is described in the document “Positioning of the SpineJack®”. Part Number: SJPOSBOOK.
Step 1: Vertebral Body Access

According to the preoperative planning strategy, a trocar is used under fluoroscopic control to determine the path to the vertebral body and to optimally position the implants (cranio-caudal angle, medio-lateral angle).

The entry point for the trocar tip should be inside the pedicle ring, close to its lateral wall, on the AP view. While moving forward in the pedicle tunnel and reaching the posterior wall of the vertebral body, on the sagittal view, the tip of the trocar should be inside the pedicular ring, close to its medial wall, on the AP view.

Access to the vertebral body requires a pedicle with a minimum diameter of at least 5 mm. (See page 6, ‘Vertebra dimensions’)

• Access for both implants can be performed before implant site preparation.
• Fluoroscopic control needs to be used at every step of vertebral body access.
• Caution should be taken to avoid anterior wall perforation while the guidewire is inserted.

**TIPS & TRICKS**

2. In wedge fractures, place implants as anterior as possible, since they retract slightly when opening.

- Insert the trocar through the pedicle ½ of the depth of the vertebral body.
- Remove the inner part of the trocar.
- Assemble the guide wire with its handle.
- Insert the guide wire through the trocar into ½ of the depth of the vertebral body.
- Remove the guide wire handle, followed by the tube portion of the trocar.
- Slide the square awl along the guide wire to the vertebra.
- Rotate the square awl to open the surface of the cortical bone.
- Remove the square awl.
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Step 2: Implant Site Preparation

• Slide the reamer/working preassembled cannula onto the guide wire.
• Rotate the ensemble to drill into (1/3 of) the vertebral body.
• Remove the guidewire.

• Continue to drill until the desired depth for the implant is reached.

• Clean the implant’s site with the template.

TIPS & TRICKS

1. Disconnect the reamer from the working cannula.
2. Unscrew and pull to remove the reamer from the vertebra, leaving the working cannula in place. The working cannula remains in place to act as a guide for the following instruments.

3. Multi controlled implant positioning: the instrumentation has been developed to always give full control over the implant positioning. The reamer and template will give you the exact positioning of the implant.

4. Beware NOT to push working cannula deeper accidentally after drilling, as the next steps will be adapted to working cannula position (template, etc.)

• Insert the Cannula Plug* to the same depth as the template in order to:
  - Stop the bleeding while the second implant site path is prepared.
  - Visualize the depth of the first implant in order to position the second implant accordingly (radiopaque marker).
  - Stabilize the working cannula on the first site while the second implant site is prepared.
• Repeat the preparation steps for the second implant site.
Caution should be taken not to advance the guidewire while drilling with the reamer.

The reamer’s working end is the same length as the implant.

The preparation of both implant sites can be performed before the placement of the actual implants.

The same reamer is used for both implant site preparations, and should therefore be assembled with the second working cannula for the second implant site preparation.

Fluoroscopic controls must be used at all times throughout the implant site preparations.

* The Cannula Plug is an optional additional instrument available to facilitate the procedure and should be ordered separately.

**Step 3: Implant Insertion & Expansion**

- Insert an implant expander into each prepared path. The implant expander’s grey handle represents the axis of expansion of the implant, therefore caution should be taken to ensure that the desired orientation of expansion is achieved.

- Begin the expansion of the implants simultaneously by rotating the expanders’ blue T-handles clockwise.

- Continue turning the T-handles until the desired vertebral body reduction is achieved.

- Fluoroscopic controls should be used regularly throughout the implant’s insertion and expansion to ensure correct positioning and expansion according to the fracture reduction desired.

- After each handle rotation, allow time for the bone to adjust to the implant’s expansion.

- Once the expansion of the implant has started the implant cannot be closed again.

**TIPS & TRICKS**

5. After having finalized the “bed of the implant” with the template, move the instrument gently in a cranio-caudal motion to ease the opening of the implant in the next step.

6. SpineJack® blades have been designed to allow for plastic deformations in order to adapt to the patient-specific bone conditions and vertebral endplate shape.
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Step 4/Expander Removal

1. Completely unscrew the expander’s blue T-handle until the implant is no longer attached.
2. Remove the inner rod of the implant expander, leaving in place the working cannula and the implant expander’s outer sleeve.

Step 5/Cement Preparation & Injection

It is strongly recommended to use the SpineJack® System in combination with Cohesion® Bone Cement (Ref. CM0300 distributed by Vexim).

Cohesion® Bone Cement has been specifically developed for use with SpineJack® to optimize the safety of cement injection.

- Prepare the cement.
- TC05003: fill the desired quantity of cement fillers.
- TC05004: connect to the delivery system.

The cement fillers are additional instruments and should be ordered separately.

TIPS & TRICKS

7. In rare cases, bone conditions could lead SpineJack® to deploy asymmetrically. No remedial action is needed. Injection of cement can be done as usual. A safety release mechanism is incorporated in the design of the implant fixation thread and will work by releasing the implant from the implant holder shaft when excessive force is applied (>200kg).

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Step 5: Cement Preparation & Injection

- For SpineJack® 5mm and 6.5mm insert the cement fillers into working cannula/implant expander.
- For SpineJack® 4.2mm connect the TC05005 to the supplied TC04004 adaptor.
- TC05003/TC05005: Push the mandrel to inject the cement.
- TC05004: Inject cement using delivery system.
- Remove empty cement filler.
- Insert another cement filler and continue cement injection.
- Continue the process until the desired quantity of cement has been injected.
- Simultaneously rotate and remove the cement pusher, the working cannula and the implant expander.
- Close the surgical access.

TIPS & TRICKS

8. Cement fillers should be rotated a few times before removal to prevent creation of a “cement mouse tail” in the pedicle.

9. Cement injection is critical to long-term results, and therefore should be injected so as to bridge the superior and inferior endplates. Fluoroscopic controls should be used during cement injection to monitor cement flow.